Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 1999 list were made in December 1998.

New Approvals

ANADA Number: 200-239

Pioneer Product:	135-780
Trade Name:	Dolorex®
Ingredients:	Butorphanol tartrate
Sponsor:	Intervet, Inc.
Approval Date:	09/28/98
Status:	Prescription only
Route:	Intravenous
Species:	Horses
Drug Form:	Liquid (solution)
Concentration:	10 mg/mL
Indications:	For the relief of pain associated with colic in adult horses and yearlings and postpartum pain in mares.

21CFR 522.246

ANADA Number: 200-261

Pioneer Product:	140-859
Trade Name:	ChlorMax™/ Bio-Cox®
Ingredients:	Chlortetracycline, salinomycin
Sponsor:	Alpharma, Inc.
Approval Date:	09/21/98
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Article to make Type C Medicated Feed
Concentration:	Chlortetracycline: 50, 65, and 70 g/lb in Type A Medicated Articles Salinomycin: 30 and 60 g/lb in Type A Medicated Articles
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati* and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments.
Tolerance:	21CFR 556.150 Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat. Salinomycin does not require a tolerance.
Withdrawal:	1 day

This ANADA provides for the combined use of two approved Type A Medicated Articles in Type C Medicated Feeds, rather than a premix incorporating both of these compounds.

21CFR 558.550

ANADA Number: 200-262

Pioneer Product:	200-095
Trade Name:	ChlorMax™/ Sacox®
Ingredients:	Chlortetracycline, salinomycin sodium
Sponsor:	Alpharma, Inc.
Approval Date:	09/21/98
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Article to make Type C Medicated Feed
Concentration:	Chlortetracycline: 50, 65, and 70 g/lb in Type A Medicated Articles Salinomycin: 30 and 60 g/lb in Type A Medicated Articles
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati* and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments.
Tolerance:	21CFR 556.150 Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat. Salinomycin does not require a tolerance.
Withdrawal:	1 day

This ANADA provides for the combined use of two approved Type A Medicated Articles in Type C Medicated Feeds, rather than a premix incorporating both of these compounds.

21CFR 558.550

ANADA Number: 200-263

Pioneer Product:	121-553
Trade Name:	ChlorMax™/ Coban®
Ingredients:	Chlortetracycline, monensin sodium
Sponsor:	Alpharma, Inc.
Approval Date:	09/21/98
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C Medicated Feeds
Concentration:	Chlortetracycline: 50, 65, and 70 g/lb in Type A Medicated Article Monensin: 60 g/lb in Type A Medicated Article
Indications:	As an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments and in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*
Tolerance:	21CFR 556.150 Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat. 21CFR 556.420 Monensin: A tolerance for residues is not needed. The safe concentrations for total residues in the edible tissue is 1.5 ppm in muscle, 4.5 ppm in liver, and 3.0 ppm in skin with adhering fat.
Withdrawal:	1 day

21CFR 558.355

NADA Number: 141-002

Trade Name:	OXY 500 Calf Bolus / OXY 1000 Calf Bolus
Ingredients:	Oxytetracycline HCl
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	10/26/98
Status:	Over-the-counter
Route:	Oral
Species:	Beef and dairy calves
Drug Form:	Bolus (tablet)
Concentration:	500 and 1000 mg/bolus
Indications:	For the control and treatment of the following diseases caused by organisms sensitive to oxytetracycline: bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis); bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.
Tolerance:	21CFR 556.500: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney.
Withdrawal:	Zero days

21CFR 520.1660c

Supplemental Approvals

ANADA Number: 200-147

Trade Name:	Genta-Ject™
Ingredients:	Gentamicin sulfate
Sponsor:	Merial Ltd.
Approval Date:	10/30/98
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Turkeys
Drug Form:	Liquid (solution)
Concentration:	100 mg/mL
Indications:	As an aid in the prevention of early mortality of 1 to 3 day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.
Withdrawal:	At least 9 weeks after treatment.

This supplemental application provides for the addition of a new species (turkeys).

21CFR 522.1044

NADA Number: 141-095

Trade Name:	Dectomax® 0.5% Pour-On Solution for Cattle
Ingredients:	Doramectin
Sponsor:	Pfizer, Inc.
Approval Date:	10/25/98
Status:	Over-the-counter
Route:	Topical
Species:	Beef cattle and non-lactating dairy cattle
Drug Form:	Liquid (solution)
Concentration:	5 mg/mL
Indications:	Gastrointestinal Roundworms: *Ostertagia ostertagi* (adults and L4, including inhibited larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and L4), *Trichostrongylus axei (*adults), *Trichostrongylus colubriformis* (adults and L4), *Cooperia oncophora* (adults and L4), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and L4), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and L4), Trichuris spp. (adults). Lungworms: *Dictyocaulus viviparus (*adults and L4). Eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults). Grubs: *Hypoderma bovis, Hypoderma lineatum.* Lice: Biting lice: *Damalinia bovis*; sucking lice: *Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus.* Mange mites: *Chorioptes bovis, Sarcoptes scabiei.*
Tolerance:	21CFR 556.225: 0.1 ppm parent doramectin (the marker residue) in liver (the target tissue) and 30 ppb in muscle of cattle. The Acceptable Daily Intake (ADI) is 0.75 mcg/kg body weight/day for total residues of doramectin.
Withdrawal:	45 days
Patent number:	5,089,480 Expiration date: 02/18/2009
Exclusivity:	3 years

This supplemental application provides for the addition of treatment and control of horn flies, *Haematobia irritans*.

21CFR 524.77 and *556.225*

NADA Number: 141-061

Trade Name:	Dectomax® 1% Injectable Solution for Cattle and Swine
Ingredients:	Doramectin
Sponsor:	Pfizer, Inc.
Approval Date:	10/25/98
Status:	Over-the-counter
Route:	Subcutaneous or intramuscular for cattle, intramuscular only for swine
Species:	Beef cattle and non-lactating dairy cattle, swine
Drug Form:	Liquid (solution)
Concentration:	10 mg/mL
Indications:	**Cattle:** For the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice and mange mites : Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi, O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, T. longispicularis, Cooperia oncophora, C. pectinata, C. punctata, C. surnabada, Bunostomum phlebotomum, Strongyloides papillosus, Oesophagostomum radiatum, Trichuris* spp. Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*. Eyeworms: *Thelazia* spp. Grubs (parasitic stages): *Hypoderma bovis, H. lineatum*. Sucking lice: *Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus*. Mange mites: *Psoroptes bovis, Sarcoptes scabie*i. Dectomax injectable solution has been proved to effectively control infections and to protect cattle

from reinfection with *Ostertagia ostertagi* for 21 days after treatment, and *Cooperia punctata* and *Dictyocaulus viviparus* for 28 days after treatment.

NADA Number: 141-061, con't

Swine: For the treatment and control of the following nematode and arthropod parasites:
Gastrointestinal roundworms: *Hyostrongylus rubidus* (adults), *Ascaris suum* (adults and 4th stage larvae), *Oesophagostomum dentatum* (adults and 4th stage larvae), *Oesophagostomum quadrispinulatum* (adults), *Strongyloides ransomi* (adults).
Lungworms: *Metastrongylus* spp. (adults).
Kidney worms: *Stephanurus dentatus* (adults).
Sucking lice: *Haematopinus suis* (adults and immature stages).
Mange mites: *Sarcoptes scabie*i var. suis (adults and immature stages).

Tolerance: 21CFR 556.225: 0.1 part per million (ppm) for parent doramectin (marker residue) in liver (target tissue) of cattle, 30 ppb in muscle of cattle and 0.16 ppm in liver of swine. The Acceptable Daily Intake (ADI) is 0.75 mcg/kg body weight/day for total residues of doramectin.
Withdrawal: 35 days
Patent number: 5,089,480 Expiration date: 02/18/2009
Exclusivity: 3 years

This supplemental application provides for the addition of persistent efficacy to protect cattle from reinfection with *Cooperia oncophora* for 14 days and *Oesophagostomum radiatum* for 28 days after treatment.

21CFR 522.770 and *556.225*

Suitability Petition Action

Number: **98P-0862/CP1**
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, ivermectin/pyrantel (Heartgard™ Plus), Merial Limited, NADA 140-971, by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.
Action: Approved on 12/18/98.

Number: **98P-0927/CP1**
Sponsor: Heska Corporation
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, ivermectin/pyrantel (Heartgard™ Plus), Merial Limited, NADA 140-971, by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.
Action: Approved on 12/18/98.

Number: **98P-1037/CP1**
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug trimethoprim/sulfadiazine which differs from the listed product, trimethoprim/sulfadiazine (Uniprim™), Macleod Pharmaceuticals, Inc., ANADA 200-033 by the following characteristic: Trimethoprim/sulfadiazine generic differs in dosage form from the listed product.
Action: Filed on 11/23/98.

Number: **98P-1196/CP1**
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (Rapinovet™), Schering-Plough Animal Health Corp., NADA 141-070, by the following characteristics: Propofol generic differs in concentration and the addition of a

preservative from the pioneer product.
Action: Filed on 12/17/98.

Addition of Patent

NADA Number: 141-068

Patent Number: 5756506 Expires 06/26/2015

Technical Amendment

NADA Number: 039-402 and **140-288**

Trade Name: MGA® 500 Liquid Premix, Bovatec®
Ingredients: Melengestrol acetate, lasalocid
Sponsor: Pharmacia & Upjohn Co.
Approval Date: 12/01/98
Status: Over-the-counter
Route: Oral
Species: Heifers fed in confinement for slaughter
Drug Form: Type A medicated articles to make Type B and C medicated feeds

These supplemental applications provides for two technical amendments. The first technical amendment relates to the editing the *Special considerations* section to provide for the manufacture of both Type B and C feeds The second technical amendment relates to the manufacture of the combination of MGA and lasalocid.

21CFR 558.342